

# PATENT COOPERATION TREATY

To:

SUN PHARMACEUTICAL INDUSTRIES  
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# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)	5 April 2006 (05.04.2006)
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Applicant's or agent's file reference  
**TGB<sub>1</sub>**

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
**PCT/IN 2004/000447**

International filing date (day/month/year)  
**24 December 2004 (24.12.2004)**

Priority Date (day/month/year)  
**24 December 2003 (24.12.2003)**

International Patent Classification (IPC) or both national classification and IPC  
**C07D 409/14 (2006.01); C07D 211/42 (2006.01); C07D 333/20 (2006.01)**

Applicant

**SUN PHARMACEUTICAL INDUSTRIES LIMITED**

**1. This opinion contains indications relating to the following items:**

- ☒ Cont. No. I Basis of the opinion
- ☐ Cont. No. II Priority
- ☒ Cont. No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Cont. No. IV Lack of unity of invention
- ☒ Cont. No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Cont. No. VI Certain documents cited
- ☐ Cont. No. VII Certain defects in the international application
- ☒ Cont. No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

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**Continuation No. I**

**Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed.

**Continuation No. III:**

**Non-establishment of opinion with regard to  
novelty, NonInventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an NonInventive step (to be non obvious), or to be industrially applicable have not been examined in respect of the because no international search report has been established for said claims Nos. 18.

**Continuation No. V**

**Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step  
or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-18	YES
	Claims ---	NO
Inventive step (IS)	Claims 1-18	YES
	Claims ---	NO
Industrial applicability (IA)	Claims 1-18	YES
	Claims ---	NO

**2. Citations and explanations:**

The following documents have been cited in the Search Report:

D1: US 5 010 090 A  
D2: US 5 354 760 A  
D3: US 5 958 951 A  
D4: Journal of Medicinal Chemistry (1993), 36(12), 1716-25 (abstract).

The preparation of polymorphic forms III and IV of tiagabine hydrochloride, of tiagabine hydro-chloride acetonitrile solvate, or of amorphous tiagabine hydrochloride is neither described or suggested in the cited documents. Therefore, claims 1-18 have to be acknowledged as novel and involving an inventive step.

Industrial applicability is given.

**Continuation No. VIII:**

**Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 18 includes no technical characteristics, but refers to the complete description. According to Rule 6.2.(a) PCT, such claims are not allowed. Therefore, claim 18 should be reformulated or deleted.

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